

REMARKS

Upon entry of the present response, claims 5 and 6 will have been amended. Accordingly, claims 1, 2, 5-13, 20-26, 35, and 36 are currently pending. Claims 1, 2, 7-13, and 20-26 have been withdrawn from consideration by the Examiner as being directed to a nonelected invention. Applicants respectfully request reconsideration of the outstanding rejections and allowance of claims 5, 6, 35, and 36 in the present application. Such action is respectfully requested and is now believed to be appropriate and proper.

The Examiner has rejected claims 5 and 35 under 35 U.S.C. § 103(a) as being unpatentable over PRUITT (US 6,458,076) in view of HIRATA (US 7,591,781).

The Examiner has rejected claims 6 and 36 under 35 U.S.C. § 103(a) as being unpatentable over PRUITT (US 6,458,076) in view of HIRATA (US 7,591,781) and HARKRIDER (US 6,328,730).

Although Applicants do not necessarily agree with the Examiner's rejection of claim 5 on this ground, nevertheless, Applicants have amended independent claim 5 to clearly obviate the above noted ground of rejection in order to expedite prosecution of the present application. In this regard, Applicants respectfully submit that PRUITT and HIRATA fail to teach or suggest the subject matter claimed in amended claim 5. In particular, claim 5, as amended, sets forth an internal treatment apparatus having a flexible tubular body to be introduced into a patient including, inter alia, "a center opening and an endoscope inserted through said center opening for observing a target site, said center opening extending through said flexible tubular body from a center of a distal end face of said flexible tubular body, said distal end face facing said target site, and a plurality of circumferential holes through which surgical instruments are inserted for performing a surgical procedure on said target site, each of said plurality of circumferential holes

being provided to extend through a side face of said flexible tubular body at said distal end of said flexible tubular body so that each of said plurality of circumferential holes is independent from said distal end face, and each of said plurality of circumferential holes is distinct from said center opening".

Further, although Applicants do not necessarily agree with the Examiner's rejection of claim 6 on this ground, nevertheless, Applicants have amended independent claim 6 to clearly obviate the above noted ground of rejection in order to expedite prosecution of the present application. In this regard, Applicants respectfully submit that PRUITT, HIRATA, and HARKRIDER fail to teach or suggest the subject matter claimed in amended claim 6. In particular, claim 6, as amended, sets forth an internal treatment system including, *inter alia*, "a flexible tubular body to be introduced into a patient, said flexible tubular body including a center opening and an endoscope inserted through said center opening for observing a target site, said center opening being circular in cross section and extending through said flexible tubular body from a center of a distal end face of said flexible tubular body, said distal end face facing said target site, and a plurality of circumferential holes through which surgical instruments are inserted for performing a surgical procedure on said target site, each of said plurality of circumferential holes being provided to extend through a side face of said flexible tubular body at said distal end of said flexible tubular body, so that each of said plurality of circumferential holes is independent from said distal end face, and each of said plurality of circumferential holes is distinct from said center opening; a body manipulating device for manipulating said flexible tubular body from outside said patient; an endoscope manipulating device for manipulating said endoscope from outside said patient; and a surgical instrument manipulating device for manipulating said surgical instruments from outside said patient".

This amendment is fully supported by the specification, including the claims and drawings, and no prohibited new matter has been added.

As shown in figures 7-14, the internal treatment apparatus and system of the instant invention includes a flexible tubular member with a distal end portion 111, circumferential holes 131, 132 opening on the side surface of the flexible tubular body and extending through the flexible tubular body, a center opening 220 extending through the center of the flexible tubular member, and a stereoscopic endoscope 221 inserted through the center opening for observing a target site. Surgical instruments 242 and 241 pass through the circumferential holes 131, 132.

The PRUITT patent discloses an endoscope 10 having a handle 12, a shaft 14 including a central lumen 20, and auxiliary lumens 21-28. As shown in the drawings and as described in the patent, PRUITT does not teach an endoscope inserted through the central lumen 20. Accordingly, the PRUITT patent fails to teach or suggest a central opening and an endoscope inserted through said center opening for observing a target site, as in Applicants' claimed invention.

In the Official Action dated September 8, 2011 and in the Advisory Action dated October 27, 2011, the Examiner has taken the position that the center opening 20 of the PRUITT device is fully capable of receiving an endoscope therethrough. However, it is respectfully submitted that the center opening 20 is *not* capable of receiving an endoscope therethrough at least since it would not be appropriate to insert another endoscope in the endoscope 10 of PRUITT. Moreover, contrary to the Examiner's assertions, neither is it a common practice to insert another endoscope in an endoscope. Further, claims 5 and 6, as amended, set forth "a center opening and an endoscope inserted through said center opening for observing a target site", thus requiring an endoscope in addition to a center opening. In other words, claims 5 and 6, as currently amended,

require an endoscope inserted in the center opening, and even an instrument with a center opening that would be capable of receiving an endoscope *still* would fail to meet the requirements of the claim language. Thus, even assuming, arguendo, that the center opening 20 of PRUITT was capable of receiving an endoscope therein, the center opening does not in fact have an endoscope inserted therethrough, as required by the amended claims 5 and 6. Merely being capable of receiving an endoscope does not meet the requirement that the device include an endoscope.

Additionally, in the Advisory Action dated October 27, 2011, the Examiner contends that an endoscope apparatus being inserted into another endoscope is common practice within the art, as evidenced by KOMI (US 4,979,496); and that a combination including insertion of an endoscope 20 of KOMI into the center lumen 20 of PRUITT would be an obvious combination. However, it is respectfully submitted that KOMI fails to teach or suggest an endoscope inserted in another endoscope. The Examiner has pointed to figure 4 as showing an endoscope in another endoscope. However, figure 4 shows an insertion unit 2 having a flexible core bar 11 within a guide tube 9. The insertion unit 2 and guide tube 9 are inserted in duodenum 100, the pancreatic duct 102, and the bile duct 103 of the patient. Therefore, figure 4 of KOMI shows the insertion unit 2 inserted in the body of a patient, and fails to show an endoscope inserted in another endoscope. Further, it is also believed that the guide tube 9 within the insertion unit 2 could not fairly be considered an endoscope inserted in another endoscope. Accordingly, it is respectfully submitted that, contrary to the Examiner's assertions, KOMI fails to teach or suggest an endoscope inserted in another endoscope, and a combination including the insertion of an endoscope in another endoscope is not a common practice. Therefore, a combination of PRUITT

including an endoscope in another endoscope would not have been obvious to one having ordinary skill in the art.

Accordingly, PRUITT fails to teach an internal treatment apparatus having a flexible tubular body including, *inter alia*, “a center opening and an endoscope inserted through said center opening for observing a target site”, as set forth in amended claim 5.

Further, as recognized by the Examiner, the PRUITT patent fails to teach or suggest a plurality of circumferential holes that extend through the side face of the flexible tubular body.

The HIRATA patent is directed to an endoscope with insertion direction changing guides. However, the HIRATA patent does not disclose or teach a flexible tubular body with a plurality of circumferential holes on the side face thereof. In the HIRATA device, the lumen 91a is provided on the guide member 10, as shown in figure 9A. The guide member determines the forward moving direction of the endoscope 2 in the body cavity; the guide member 10 does not have a center opening. In the HIRATA device, if the endoscope 2 can move straight ahead into the body cavity, or if there is no need to bend the endoscope 2 in the body cavity, the guide member 10 would then be unnecessary. The guide member 10 (the guide tube 124) is provided for allowing the endoscope 2 to pass therethrough toward a desired direction. Although HIRATA shows a plurality of lumens, HIRATA does not disclose or teach a structure in which the endoscope passes through one lumen and, simultaneously, a surgical instrument passes through another lumen, as in the present invention. Thus, the guide member 10 of HIRATA is not equivalent to an internal treatment apparatus, as claimed. Thus, contrary to the Examiner’s assertions, HIRATA fails to teach or suggest lateral circumferential holes in a side face of a flexible tubular body having a center opening.

Accordingly, the HIRATA patent fails to cure the deficiencies of the PRUITT device, and even assuming, arguendo, that the teachings of PRUITT and HIRATA have been properly combined, Applicants' claimed internal treatment apparatus would not have resulted from the combined teachings thereof.

Further, there is nothing in the cited prior art that would lead one of ordinary skill in the art to make the modification suggested by the Examiner in the rejection of claim 5 under 35 U.S.C. § 103(a) over PRUITT in view of HIRATA. Thus, the only reason to combine the teachings of PRUITT and HIRATA results from a review of Applicants' disclosure and the application of impermissible hindsight. Accordingly, the rejection of claim 5 under 35 U.S.C. § 103(a) over PRUITT in view of HIRATA is improper for all the above reasons and withdrawal thereof is respectfully requested.

Further, the HARKRIDER patent fails to teach or suggest a body manipulating device, an endoscope manipulating device, and a surgical instrument manipulating device as claimed. In particular, the HARKRIDER patent is directed to a surgical catheter having multiple lumens. Additionally, the HARKRIDER patent fails to teach or suggest a center opening and an endoscope inserted in a center opening in an internal treatment system, as set forth in amended claim 6. Thus, HARKRIDER fails to teach or suggest a body manipulating device, an endoscope manipulating device, and a surgical instrument manipulating device as claimed.

Therefore, the HIRATA and HARKRIDER patents fail to cure the deficiencies of the PRUITT device, and even assuming, arguendo, that the teachings of PRUITT, HIRATA, and HARKRIDER have been properly combined, Applicants' claimed internal treatment apparatus would not have resulted from the combined teachings thereof.

Further, there is nothing in the cited prior art that would lead one of ordinary skill in the art to make the modification suggested by the Examiner in the rejection of claim 6 under 35 U.S.C. § 103(a) over PRUITT in view of HIRATA and HARKRIDER. Thus, the only reason to combine the teachings of PRUITT, HIRATA, and HARKRIDER results from a review of Applicants' disclosure and the application of impermissible hindsight. Accordingly, the rejection of claim 6 under 35 U.S.C. § 103(a) over PRUITT in view of HIRATA and HARKRIDER is improper for all the above reasons and withdrawal thereof is respectfully requested.

Applicants submit that dependent claims 35 and 36, which are at least patentable due to their dependency from claims 5 and 6, for the reasons noted above, recite additional features of the invention and are also separately patentable over the prior art of record based on the additionally recited features. Accordingly, claims 35 and 35 are separately patentable for these additional reasons.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections, and an early indication of the allowance of claims 5, 6, 35, and 36.

SUMMARY AND CONCLUSION

In view of the foregoing, it is submitted that the present response is proper and that none of the references of record, considered alone or in any proper combination thereof, anticipate or render obvious Applicants' invention as recited in claims 5, 6, 35 and 36. The applied references of record have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

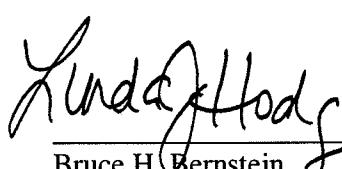
Accordingly, consideration of the present response, reconsideration of the outstanding Official Action, and allowance of all of the claims in the present application are respectfully requested and now believed to be appropriate.

Any amendments to the claims which have been made in this amendment, which do not narrow the scope of the claims, and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered cosmetic in nature, and to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

Applicants have made a sincere effort to place the present application in condition for allowance and believe that they have now done so.

Should there be any questions, the Examiner is invited to contact the undersigned at the below listed number.

Respectfully Submitted,
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